

### **REMARKS**

Claims 1-17 and 19-29 were pending in the application; claims 3-6, 22, and 23 are withdrawn. Support for amendment to claim 25 is in paragraph [0087] of the specification. No new matter is entered herein.

#### **I. Drawings**

The drawings were objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include particular reference signs mentioned in the description. For the sake of brevity for this particular drawing, Applicants amend the specification to reflect that the repeating structures in the figure correspond to a particular element's letter (*a, b, c, d, etc.*) as the figure is viewed from left to right. Applicants assert that this is not new matter, as one of skill in the art would recognize that it is an obvious demarcation based at least on exemplary elements 101 (*a* and *h*), 109 (*a* and *h*), and 114 (*e* and *g*), for example.

Applicants respectfully request withdrawal of the objection.

#### **II. 35 USC § 112, second paragraph**

Claim 25 was rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. In particular, the Examiner considered it unclear what the groups would be selected from other than streptavidin-binding compounds.

Claim 25 is amended herein accordingly, and Applicants respectfully request withdrawal of the rejection.

#### **III. 35 USC § 103(a)**

##### **A. Claims 1, 2, 8-17, 19-21, 25-27, and 29**

Claims 1, 2, 8-17, 19-21, 25-27, and 29 were rejected under 35 USC § 103(a) as allegedly being unpatentable over Andersson *et al.* (US2003/0053934; "Andersson") in view of Yager *et al.* (US. 2003/0124623; "Yager").

The Examiner considers the rejected claims to be unpatentable over the combination of Andersson, which is cited for teaching a microfluidic device having a porous matrix and a packed bed of monosized particles, with Yager, which concerns microchannels in a

microfluidic device having a storage unit in the wall of the channel wherein a plug is fixed (see claim 1 of Yager); the plug is dissolvable and can diffuse into a carrier fluid flowing in the channel ([0018] of Yager).

In Andersson, the invention therein concerns controlled liquid flow in parallel through microchannels of a microfluidic device such that the flow rate of liquid aliquots therethrough is adjusted to give pressure drop in restriction microconduits. The reference gives no consideration or motivation whatsoever for a problem or need for preserving a wet porous bed. The Examiner arbitrarily contends that one of skill in the art would see a need for a bed-preserving agent. However, the skilled artisan is given *no guidance from Andersson that such a need even exists*, so there would be **no reason to seek resolution of an unrecognized problem**. In paragraphs [0081]-[0084] where the solid phase is discussed, or anywhere else in Andersson for that matter, there is no consideration that an agent to preserve the bed would be necessary.

Yager, on the other hand, concerns a microfluidic device that employs a solid reagent plug in a storage area of a channel, wherein the plug comprises a matrix and a reagent having affinity for an analyte. In specific embodiments, the plug is a solid form of a reagent solution (paragraphs [0023]-[0029]. Furthermore, the plug in certain embodiments includes preservatives ([0089]), which Yager notes is for a compound that "...preserve(s) the function of the reagent during storage." ([0090]). Thus, Yager is related to preservation of reagents (p. 6, [0103]), not to adherence of particles. As seen from at least FIGS. 5 and 6 of Yager, element 117 represents "analyte particles" and element 270 represents "analyte molecules," and these should not be confused with the solid phase material of the present invention.

The Examiner admits that Andersson fails to teach that the porous particles comprise a bed-preserving agent comprising a compound exhibiting a hydrophilic group and that is water-soluble (page 4 of the Action). Applicants assert that Andersson provides no reason to the skilled artisan to do anything differently than the methods that Andersson employed. Andersson gives no teaching that there could be damages to a porous bed upon drying/dehydration and storage, so there is no reason for the skilled artisan to seek any resolution of this problem. Therefore, there is no reason for the skilled artisan to achieve the combination of Andersson and Yager when Andersson fails to send the skilled artisan to seek

remedy for problems associated with predispensing, drying, storage, transportation, and/or reconstitution of solid phase materials, including to at least Yager.

Thus, Applicants therefore argue that the present invention is inventive over the cited references. Applicants respectfully request withdrawal of the rejection.

**B. Claims 7, 24, and 28**

Claims 7, 24, and 28 were rejected under 35 USC § 103(a) as allegedly being unpatentable over Andersson in view of Yager and further in view of Glezer *et al.* (U.S. 2004/0189311).

Applicants address above the rejection over the combination of Andersson and Yager and assert that Glezer fails to teach, suggest, or provide motivation for the subject matter that is lacking in the combination of Andersson and Yager.

Applicants respectfully request withdrawal of the rejection.

**IV. Double Patenting**

Claims 1, 8, and 16-17 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of co-pending Application No. 10/550,182.

A "provisional rejection" is unlike a regular rejection in that it is contingent upon an event unrelated to the prosecution of the present application that may never come to pass, while a regular rejection is made in view of facts actually in existence at the time the rejection is made. A provisional double-patenting rejection is based on the claims of a co-pending application as originally filed. Because the co-pending application may never actually issue, or, alternatively, the claims as originally filed may be amended during the course of prosecution of the co-pending application such that the claims, when issued, no longer impact Applicants' claims, the rejection remains "provisional" until the co-pending application issues. If the issued application still results in a double-patenting rejection, the provisional status of the rejection is removed, and the rejection becomes a regular double-patenting rejection. Once the rejection is made non-provisional, Applicants are then able to address fully the double-patenting concerns with regard to the substance of the claims that

have actually issued in the referenced patent. The Office and Applicants are saved from needless speculation as to whether the co-pending application will actually issue or what the substance of the final issued claims will be. As such, Applicants are not required to address the merits of the provisional double-patenting rejections until such time as the co-pending applications actually *issue*.

Indeed, while M.P.E.P. § 804 allows for the merits of the rejection to be addressed while the rejection remains provisional ("[t]he merits of such a provisional rejection can be addressed by both the applicant and the examiner without waiting for the first patent to issue"), the Court of Claims and Patent Appeals (now the Court of Appeals for the Federal Circuit) has stated: "Once the provisional rejection has been made, there is nothing the examiner and the applicant **must** do until the other application issues." *In re Mott*, 190 U.S.P.Q. 536, 541 (C.C.P.A. 1976) (emphasis added). M.P.E.P. § 804 allows for the prosecution to continue while a provisional double-patenting rejection is pending and even instructs the Office to continue to make such a provisional rejection until one of the applications issues as a patent. For example, M.P.E.P. § 804 states:

The "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in one of the applications. If the "provisional" double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the "provisional" double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent."

Applicants submit that it is proper for the Office to continue prosecution in light of the provisional status of the rejections and to allow Applicants to address the merits of the double-patenting rejection at such time as the co-pending application(s) actually issue.

The courts have endorsed the appropriateness of the Office allowing the provisional rejection to remain standing during prosecution until the co-pending application actually issues. For example, in *In re Wetterau*, 148 U.S.P.Q. 499 (C.C.P.A. 1966), the Court of

Customs and Patent Appeals held that a provisional double-patenting rejection in view of a co-pending application was proper. Even though the claims of the co-pending application had already been *allowed*, the court stated, "no assurance can be given that the status will endure and a patent containing such claims will ultimately issue." 148 U.S.P.Q. at 501. The court found the uncertainty of the co-pending application's status was sufficient to allow the provisional rejection to remain standing and to prevent the applicant from having to abandon the case. In holding such, the court stated:

If a patent were not to issue on the Carabateas [co-pending] application, the "double patenting" rejection, if here affirmed, would of necessity evaporate for the possibility of two patents would not exist. Grave injury to applicant's rights might occur if the Wetterau [applicant's] application were to go abandoned through no fault of the applicant prior to the issuance of Carabateas, the reference application.

*Id.*

In view of the above, Applicants submit that they have acknowledged the provisional double-patenting rejections and, further, that it is clear Applicants are not required to address the merits of the provisional double-patenting rejections until such time as the co-pending application(s) issue and the rejections are made non-provisional.

## **V. Conclusion**

Applicants assert that the pending claims are suitable for allowance and respectfully request withdrawal of all rejections.

Applicant believes no fee is due with this response other than the fee for the Petition for Extension of Time of Three Months. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02773US1 from which the undersigned is

Application No.: 10/550,137

Docket No.: HO-P02773US1

authorized to draw.

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Respectfully submitted,

By\_\_\_\_/Melissa L. Sistrunk/\_\_\_\_\_

Melissa L. Sistrunk

Registration No.: 45,579

FULBRIGHT & JAWORSKI L.L.P.

Fulbright Tower

1301 McKinney, Suite 5100

Houston, Texas 77010-3095

(713) 651-3735

(713) 651-5246 (Fax)

Agent for Applicant